

Appl. No. 09/489,667  
Reply to Office Action of October 24, 2005

## BEST AVAILABLE COPY

### Remarks

#### Introduction

Claims 69-80 were pending and have been allowed. However, in the October 24, 2005 Office Action, claims 69-80 have been indicated as potentially interfering with at least claim 5 of U.S. Patent No. 6,632,440 (the '440 patent).

By way of this response, claims 69, 71-73, and 75-76 have been amended, and claims 70 and 74 have been cancelled without prejudice. Claims 69, 71-73 and 75-76 have been amended to recite that the agent for treating pain comprises a modified botulinum neurotoxin which comprises a botulinum neurotoxin H<sub>u</sub>, a botulinum neurotoxin L chain, and no functional H<sub>c</sub> domain. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added.

In view of the above, claims 69, 71-73, and 75-80 are currently pending.

#### Potential Interference with '440 Patent

In the October 24, 2005 Office Action, the claims of the present application were indicated as potentially interfering with at least claim 5 of the '440 Patent since both sets of claims encompassed a modified clostridial neurotoxin comprising a clostridial neurotoxin without a functional H<sub>c</sub> domain, covalently coupled to substance P. The Office Action further describes in detail the language of previous claim 69 of the present application in relation to claim 5 of the '440 Patent. The Office Action acknowledges that claim 5 of the '440 Patent, and the claims dependent therefrom, recite that the compound is not a botulinum toxin.

Appl. No. 09/489,667  
Rcply to Office Action of October 24, 2005

**BEST AVAILABLE COPY**

As set forth herein, applicant has amended independent claim 69 to specifically recite that the agent comprises a modified botulinum neurotoxin. Thus, applicant submits that each of the present claims recite an agent that comprises components of a botulinum neurotoxin, such as a botulinum neurotoxin translocation domain (e.g., H<sub>N</sub> domain), a botulinum neurotoxin proteolytic domain (e.g., a light chain), and combinations thereof.

Applicant submits that the present claims do not interfere with any of the claims of the '440 Patent. Therefore, applicant respectfully requests the Examiner to reconsider the decision regarding the potential interference and to proceed to pass the present application to issuance.

Applicant submits that the present claims are not directed to the same invention or the same subject matter claimed in the '440 Patent. In other words, applicant submits that the presently claimed invention is a separate patentable invention relative to the invention claimed in the '440 Patent.

As discussed herein, each of the claims of the '440 Patent recites "with the proviso that the compound is not a botulinum toxin". Thus, the compounds claimed in the '440 Patent are not botulinum toxins. Therefore, the compounds claimed in the '440 Patent are different and distinct from the claimed agents of the present application, which comprise a botulinum neurotoxin or components thereof.

Claim 5 of the '440 Patent depends from independent claim 4. Claim 4 is set forth below:

4. A compound which inhibits mucus secretion by mucus secreting cells, said compound comprising:
  - (a) a light chain (L-chain) or L-chain fragment of a clostridial neurotoxin, which L-chain or L-chain

**BEST AVAILABLE COPY**

Appl No. 09/489,667

Reply to Office Action of October 24, 2005

fragment comprises the active proteolytic enzyme domain of the L-chain;

(b) a targeting domain that selectively binds to a target cell that is a mucus secreting cell; and

(c) a translocating domain of a clostridial neurotoxin that translocates the L-chain or L-chain fragment into the target cell;

with the proviso that the compound is not a botulinum toxin.

Based on the language of claim 4 of the '440 Patent, it is apparent that, either the light chain or light chain fragment, the translocation domain, or both, are not botulinum toxin light chains or light chain fragments, or botulinum toxin translocation domains, or both.

However, claim 6 (which depends from claim 4) of the '440 Patent states that the translocating domain comprises the H<sub>2</sub> domain of a botulinum polypeptide. Since claim 4 is necessarily broader in scope than dependent claim 6, claim 4 recites a translocation domain that is not of a botulinum toxin. Furthermore, since the light chain or light chain fragment recited in claim 4 is of a clostridial neurotoxin in general, and since claim 4 specifically states that the compound is not a botulinum toxin, the light chain or light chain fragment must also not be of a botulinum toxin. Claim 5 of the '440 Patent is dependent from claim 4, and therefore, claim 5 of the '440 Patent includes all of the elements recited in claim 4, including those elements described above.

In direct contrast, the present claims of the present application specifically recite that the agent comprises a botulinum neurotoxin or components thereof. Applicant submits that the claimed invention of the '440 Patent actually teaches away from the present claims since each of the claims of the

Appl. No. 09/489,667  
Reply to Office Action of October 24, 2005

## BEST AVAILABLE COPY

'440 Patent specifically recite that the compound is not a botulinum toxin.

With respect to the comments made in the October 24, 2005 Office Action, applicant submits that the claims of the '440 Patent would not anticipate the present claims since the claims of the '440 Patent do not disclose or teach each and every element recited in the present claims. For example, the claims of the '440 Patent do not disclose or teach an agent that comprises a botulinum neurotoxin, as recited in the present claims. In addition, applicant submits that the present claims are unobvious from and patentable over the claims of the '440 Patent, and at least claim 5 in particular, since the claims of the '440 Patent specifically teach away from the present claims by the recitation of the proviso that the compound is not a botulinum toxin.

In view of the above, applicant submits that the present claims are directed to a separate patentable invention than the invention recited in the claims of the '440 Patent. Therefore, applicant respectfully requests that an interference not be declared, and that the present application proceed to issuance.

In addition, in view of the above, applicant submits that a showing under 37 CFR § 41.202(d) is not required since the present claims and the claims of the '440 Patent are directed to separate patentable inventions.

### Conclusion

In conclusion, applicant has shown that the present claims are directed to a separate patentable invention compared to the claimed invention of the '440 Patent, that a showing under 37 CFR § 41.202(d) is not required, and that an interference between the present application and the '440 Patent should not

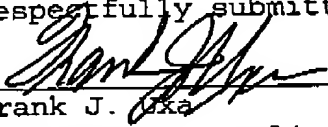
**BEST AVAILABLE COPY**

Appl. No. 09/489,667  
Reply to Office Action of October 24, 2005

be declared. Therefore, applicant submits that the present claims, that is claims 69, 71-73, and 76-80 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 1/24/06

Respectfully submitted,

  
Frank J. Uxa  
Attorney for Applicant  
Registration No. 25,612  
4 Venture, Suite 300  
Irvine, California 92618  
(949) 450-1750  
(949) 450-1764 Facsimile